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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,681	08/18/2003	Orville G. Kolterman	254/057CON	4614
44638 7590 01/25/2007 ARNOLD & PORTER LLP (18528) ATTN; IP DOCKETING DEPT. 555 TWELFTH ST, NW WASHINGTON, DC 20004			EXAMINER LIU, SUE XU	
			ART UNIT	PAPER NUMBER
			1639	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/25/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/643,681

Applicant(s)

KOLTERMAN ET AL.

Examiner

Sue Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/31/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 38-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24 and 38-40 is/are rejected.
- 7) ☒ Claim(s) 25-30 and 41-59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Status***

Claims 1-23, 31-37, and 60-69 have been cancelled;

Claims 24-30, and 38-59 are currently pending;

Claims 24-30, and 38-59 are being examined in this application.

### ***Response to Amendment***

1. Applicant's amendments to the claims and specification dated 10/31/06 are acknowledged.

### ***Election/Restriction***

2. Applicant's election with traverse of 25,28,29 tri-pro human amylin as the elected species in the correspondence dated 10/29/04 is again acknowledged and was previously made final.

### ***Priority***

3. This application is a CONTINUATION of U.S. Patent Application No. 09/576,062 (filed 5/22/2000), which is now a US PATENT, 6,608,029 (8/19/2003). The U.S. Patent Application No. 09/576,062 is a CONTINUATION of U.S. Patent Application Nos. 08/302,069 (filed 9/7/1994), which is now a US PATENT, 6,114,304 (9/5/2000). The U.S. Patent Application No. 08/302,069 is a CIP of U.S. Patent Application Nos. 08/118,381 (filed 9/7/1993), which is now abandoned.

***Withdrawn Objection (s) and/or Rejection (s)***

4. In light of Applicant's filing of Terminal Disclaimer on 10/31/06, the following ODP rejections are withdrawn:

A.) Claims 24-30 and 38-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 (especially claims 32-35) of U.S. Patent No. 6,114,304.

B.) Claims 24-30, 38, 40-57 and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 (especially claims 1-12 and 18) of U.S. Patent No. 6,417,164 .

5. In light of Applicant's amendment to the claims on 10/31/06, the following rejections are withdrawn:

A.) Claims 25-30, and 41-59 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

***Outstanding Objection (s) and/or Rejection (s)***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 24 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarantakis et al (US 4,451,394; 05/29/1984). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 7/3/06, at p. 6+.

Discussion and Answer to Argument

8. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants states "the term "amylin agonist analogue" is understood to refer to derivatives of an amylin which act as amylin agonists." (Original Spec. p.22, lines 6-8) Applicants further argue that "Thus, the term "amylin agonist analogue" describes the peptide both structurally and functionally." (Reply, pp. 12-13). Applicants further asserts that according to the above said definition, the "dodecapeptides of the '394 patent are certainly not amylin analogue" (Reply, p. 13, para 2).*

Applicants' arguments seem to rely on the word "derivatives" to convey certain structural and functional limitation. However, neither the instant specification nor the claims define the specific structural and/or functional requirements for an "amylin agonist" or an "amylin agonist analogue". For example, the instant specification does not recite any amino acid sequence requirement for a particular peptide to be either an "amylin agonist" or an "amylin agonist analogue". The only common characteristic for the claimed genus of either an "amylin agonist" or an "amylin agonist analogue" is the peptides' function such as reducing post-prandial plasma glucose levels.

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As pointed out by the applicants, the instant specification defines "Amylin agonists" as a term that "refers to compounds which mimic the effects of amylin," and "amylin itself and amylin agonist analogues may also be referred to broadly as amylin agonist." (original specification page 22, lines 3-5: substitute specification page 13-15). One amylin effect encompasses the ability of amylin to reduce post-prandial plasma glucose levels" (e.g. see original specification page 21, lines 6-12: substitute specification page 13, lines 4-8). Because the dodecapeptide taught by Sarantakis et al mimics the effects of amylin with its ability to reduce post-prandial plasma glucose as discussed in the previous Office action (mailed 7/3/06, pp. 7-8), the said dodecapeptide reads on an amylin agonist analogue according to the definition recited in the instant specification.

### ***Claim Objections***

9. Claims 25-30, and 41-59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

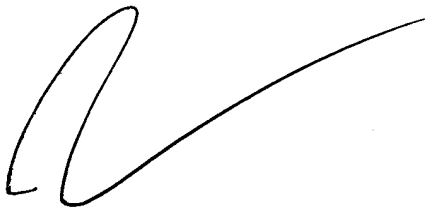
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON EPPERSON  
PRIMARY EXAMINER

SL  
Art Unit 1639  
1/17/07

A handwritten signature in black ink, appearing to be 'J. Epperson', written over the printed name.